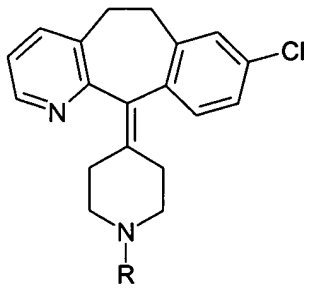
Abstract

The present invention provides substantially pure desloratadine having an HPLC purity greater than 99.5% and having an absorbance less than 0.15 Au at 420 nm for a 5%w/v solution in methanol, which does not show a peak for an impurity at a relative retention time in the range from about 0.85 to about 0.99 (relative to desloratadine appearing at a retention time of 25±5 minutes), which is greater than the discard limit set at less than 0.025% of the total area, when tested according to an HPLC method performed using a Hypersil BDS C_8 column (15cm x 4.6mm, 5 μm particle size) with the following parameters:

Mobile phase	: Buffer solution having a pH of about 3, methanol and acetonitrile in a volume ratio of 8:1:1.
Injection volume	: 20μl
Flow rate	: 1.5 ml/minute
Run time	: 75 minutes.
Discard limit	: Set at less than 0.025% of total area

The present invention also provides a process for the preparation of substantially pure desloratadine by the process comprising acidic hydrolysis of a compound of formula 3 where R is selected from COR_1, $COOR_1$ wherein R_1 is selected from branched or linear alkyl (1-6 C), cycloalkyl, alkenyl, alkynyl, aryl, aralkyl and their substituted analogs; and their substituted analogs with a strong organic acid or a mineral acid.



Formula 3